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MEDICIS PHARMACEUTICAL CORP.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IMPAX LABORATORIES, INC.,

Plaintiff,

v.

MEDICIS PHARMACEUTICAL CORP.,

Defendant.

Case No. C08-00253 MMC

REPLY IN FURTHER SUPPORT OF MEDICIS' MOTION TO DISMISS

Date: April 11, 2008
Time: 9:00 a.m.
Ctrm: #7, 19th Floor

The Honorable Maxine M. Chesney

IMPAX's opposition brief spends almost all of its ink on arguments that ignore the most fundamental issue for Medicis' motion to dismiss: whether Medicis has caused IMPAX injury-in-fact sufficient to confer constitutional standing. That is because IMPAX cannot show the required injury here. In the end, IMPAX's opposition brief is reduced to arguing that Medicis' marking of its product (which almost all companies do), general statements to the investor community of an intent to enforce its patents (again, which most companies do), and refusal to agree not to forever waive its rights (which all companies do) are sufficient to confer constitutional standing. No case has ever so held, and for good reason. Under IMPAX's theory, declaratory judgment jurisdiction would be virtually unlimited, and the courts would be flooded with requests for advisory opinions based on hypothetical facts. The law is otherwise.

I. This Court Should Dismiss IMPAX's Complaint Because IMPAX Has Not Met its Burden of Showing Declaratory Judgment Jurisdiction

A. IMPAX Cannot Show Jurisdictional Injury-in-Fact Caused by Medicis

"The core component of standing is an essential and unchanging part of the case-or-controversy requirement of Article III." Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). This "irreducible constitutional minimum of standing requires *injury-in-fact* which is concrete and particularized that is fairly *traceable to the challenged action of the defendant*, and not the result of the independent action of some third party not before the court." Id. (emphasis added). Without the allegation of an "*injury-in-fact caused by the defendant* that can be redressed by the court," there is no Article III controversy. Teva Pharm. USA, Inc. v. Novartis Pharm. Corp., 482 F.3d 1330, 1340 (Fed. Cir. 2007) (emphasis added). Thus, the Federal Circuit has held that "declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or perceives such a patent to pose a risk of infringement, *without some affirmative act by the patentee*." SanDisk Corp. v. STMicroelectronics, Inc., 480 F.3d, 1372, 1380-81 (Fed. Cir. 2007) (emphasis added). Since MedImmune, the Federal Circuit has consistently required such an "affirmative act" as a predicate to recognizing declaratory judgment jurisdiction, as discussed infra at 5-6. See, e.g., Micron Tech, Inc. v. MOSAID Techs, Inc., No. 2007-1080, 2008 WL 540182, at *3 (Fed. Cir. Feb. 29,

2008); SanDisk, 480 F.3d at 1382; Teva, 482 F.3d at 1343.

Here, IMPAX's complaint can be dismissed based on its failure to establish the required injury-in-fact that is fairly traceable to Medicis' use of its patent. Medicis has not threatened IMPAX with its patent, has not made any statements indicating an intent to sue IMPAX on its patent, and has not previously sued any entity on its patent. IMPAX does not deny that it lacks FDA approval to sell its generic copy of Solodyn®, that absent such approval IMPAX is not allowed to sell its product, that Medicis has not and cannot obtain any stay on FDA approval, and that there is nothing that Medicis has done or can do with respect to its patent rights that can impact whether FDA approves IMPAX's ANDA.

IMPAX's only assertion of "injury" is an unsupported statement in its opposition brief that "its concrete economic interest in its ANDA application is impacted by Medicis' accusation of patent infringement" and that Medicis has placed "into actual dispute the soundness of [IMPAX's] ANDA and [its] ability to secure approval of the ANDA." IMPAX Br. at 11. IMPAX provides no support for this assertion and it should be rejected for two reasons. First, as discussed further below, Medicis has never accused IMPAX of infringement and IMPAX identifies no such accusation. Not one of the public statements cited by IMPAX even mentions IMPAX. Second, and more fundamentally, even if there were an "accusation of patent infringement" by Medicis towards IMPAX (there is none), it could have no impact on whether FDA will or will not approve IMPAX's ANDA. That is entirely up to the FDA based on whether IMPAX has met the scientific and regulatory requirements; whatever Medicis has or has not said about enforcement of its patent is irrelevant.

Accordingly, contrary to IMPAX's assertion, resolution of this lawsuit would not guarantee or even expedite FDA approval; it would be irrelevant to the FDA's determination as to whether approval is appropriate. See Simon v. E. Ky. Welfare Rights Org., 426 U.S. 26, 41-42 (1976) ("The 'case or controversy' limitation of Article III . . . requires that a federal court act only to redress injury that fairly can be traced to the challenged action of the defendant, and not injury that results from the individual action of some third party not before the court."). Further, as discussed in our opening brief, Medicis cannot obtain a 30-month stay on FDA's approval of

IMPAX's ANDA, providing another reason why there is no injury to IMPAX caused by Medicis.[1] Medicis Br. at 6-7. IMPAX's opposition brief thus now makes clear that Medicis has caused no cognizable constitutional injury to IMPAX, and this case should be dismissed on that basis alone.

B. The "Totality of Circumstances" Cannot Show a Justiciable Controversy

Even if IMPAX had made a sufficient showing of constitutional injury (which it has not), IMPAX still lacks jurisdiction to sustain its declaratory judgment complaint because there is no justiciable controversy as required by MedImmune v. Genentech Inc., 127 S. Ct. 764 (2007). As discussed in our opening brief, IMPAX's submission of an ANDA cannot automatically create declaratory judgment jurisdiction; more is required. Medicis Br. at 6. The other allegations in IMPAX's opposition brief fail as a matter of law to create a justiciable controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," as MedImmune requires. IMPAX's opposition brief confirms that there has been no action by Medicis that is specifically directed at IMPAX, no statement made by Medicis to or about IMPAX that suggests an intent to sue IMPAX for patent infringement, and no prior litigation by Medicis on its patent. In sum, IMPAX identifies no "affirmative act" of aggression by Medicis that is specifically targeted at IMPAX. See SanDisk, 480 F.3d at 1380-81.

Instead, the "totality of circumstances" identified by IMPAX is no more than Medicis marking its product with its patent, making general statements to the investor community that it will protect its product and enforce its patent without any reference to IMPAX, and the absence of a promise not to sue IMPAX. Upholding jurisdiction on such facts would open up the floodgates to an endless stream of declaratory judgment complaints and place patentees in the untenable position of being dragged into court to defend the validity of their patents by doing no

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[1] IMPAX's effort to rely on its alleged "reasonable apprehension of suit" to satisfy the injury requirement should be rejected. The application of that test to determine declaratory judgment jurisdiction was rejected by the Supreme Court in MedImmune. See, e.g., SanDisk, 480 F.3d at 1380. And to the extent that IMPAX seeks to conflate this standard with the required showing of injury, that argument should also be rejected. See IMPAX Br. at 10. As discussed, the constitutional injury requirement is a separate and dispositive requirement that mandates a showing that IMPAX has suffered actual harm as a result of Medicis' conduct. There is no such showing here. Moreover, there can be no "reasonable apprehension of suit" in any event because Medicis has never accused IMPAX of infringement or even mentioned IMPAX in any of the public statements cited by IMPAX.

more than marking and generally indicating an intent to protect its rights. Finding jurisdiction in these circumstances would allow the declaratory judgment plaintiff to bring suit whenever it wishes and regardless of whether it has suffered harm at the hands of the patentee. Whatever the boundaries of declaratory judgment jurisdiction after MedImmune, they cannot be so expansive.[2] See Medicis Br. at 8.

IMPAX identifies no case that upholds a declaratory judgment claim on the basis of such flimsy and non-specific facts. Nor could it, because there is no precedent for such a holding. The Federal Circuit's post-MedImmune requirement of an "affirmative act" by the patentee that is specifically directed at the declaratory judgment plaintiff (see SanDisk, 480 F.3d at 1380-81) has been consistently applied in each of the post-MedImmune Federal Circuit cases on which IMPAX relies. There is no such "affirmative act" here. In Teva v. Novartis, the patentee engaged in the affirmative act of suing Teva on certain patents, which resulted in a 30-month-stay on FDA approval of Teva's ANDA. 482 F.3d at 1343. IMPAX incompletely quotes from Teva as holding that the "threat of litigation is a present injury creating a justiciable controversy." IMPAX Br. at 10. IMPAX omits the critical portion of the Court's statement, which makes clear that the Federal Circuit was not referring to a generalized threat of litigation, but rather a specific threat based on Novartis' prior suit against Teva that prevented Teva from entering the market. The complete quote reads: "*In light of Novartis' pending suit on the same ANDA*, this threat of litigation is a present injury creating a justiciable controversy." Teva, 482 F.3d at 1341 (emphasis added).

Similarly, in Micron Tech, Inc. v. MOSAID Techs, Inc., the patentee engaged in the affirmative acts of pursuing a "systematic licensing and litigation strategy," enforcing its patents against the three other major DRAM manufacturers over a period of four years, and sending three warning letters directly to the declaratory judgment plaintiff. No. 2007-1080, 2008

[2] IMPAX's opposition brief relies on materials that are not pled in IMPAX's complaint. As discussed in our opening brief, this motion to dismiss represents a facial attack on the allegations in IMPAX's complaint. Medicis Br. at 5-6 n.1. Even assuming that IMPAX's extra-complaint material is properly before the Court for purposes of determining whether IMPAX has properly pled jurisdiction (which Medicis does not concede), it is not sufficient to establish declaratory judgment jurisdiction.

WL 540182, at *3. And in SanDisk, the patentee directly accused the declaratory judgment plaintiff SanDisk of infringement by providing it with a detailed element-by-element infringement analyses that totaled over 300 pages in length, and further demanded a royalty from SanDisk for such infringement. SanDisk, 480 F.3d at 1382. Unlike here, each of these cases involved affirmative and specific acts of aggression by the patentee directed to the declaratory judgment plaintiff. This case is in striking contrast and there is no support for upholding jurisdiction here, where there is no affirmative act of aggression by Medicis directed at IMPAX.[3]

C. IMPAX's Declaratory Judgment Action Is Counter to the Policies of the Hatch-Waxman Act

Upholding jurisdiction here would not only run counter to the policies of the Declaratory Judgment Act, it would be inconsistent with the policies of the Hatch-Waxman Act. As discussed in our opening brief, the typical Hatch-Waxman provisions do not apply to IMPAX's ANDA filing. Medicis Br. at 3-4. In the usual scenario the patent holder would have an exclusive 45-day period in which to determine whether and where to sue, and only after expiration of that period would the generic have a right to bring an action for a declaratory judgment. 35 U.S.C. § 271(e)(5); IMPAX Br. at 7 n.8. Here, in contrast, while IMPAX is entitled to save time and money by free-riding on Medicis' data and obtaining approval based on an "abbreviated" application, IMPAX is not required to provide notice to Medicis of its ANDA with a paragraph IV certification under section 21 U.S.C. § 355(j)(2)(A). Medicis is accordingly denied the exclusive 45-day period in which to determine whether and where to sue and to obtain the typical automatic 30-month stay on FDA approval. Id. at 3, 7.

In these circumstances, where there is no paragraph IV certification and no exclusive 45-day period for the patent holder to sue, the Hatch-Waxman Act provides no basis for IMPAX to seek declaratory relief under 35 U.S.C. § 271(e)(5). Yet IMPAX tries to have it both

[3] IMPAX's citations to Kos Pharms., Inc. v. Barr Labs., Inc., 242 F. Supp. 2d 311 (S.D.N.Y. 2003) and Teva Pharms. USA, Inc. v. Abbott Labs., 301 F .Supp. 2d 819 (N.D. Ill. 2004) (IMPAX Br. at 7-8, 11), are similarly inapposite as both also involved specific affirmative conduct by the patent holder. In Kos, the patentee filed two previous actions against Barr for infringement of "not just similar, but nearly identical" patents. 242 F. Supp. 2d at 315. In Abbott, the patentee previously commenced proceedings in Canada against Teva based on the same generic product, and had a history of enforcing its rights against Teva. 301 F. Supp. 2d at 822.

ways. On the one hand, in an apparent effort create a fictional jurisdictional hook, IMPAX's opposition brief repeatedly seeks to analogize the instant framework to the typical ANDA situation. See, e.g., IMPAX Br. at 2 (IMPAX's "ANDA procedure was created by the Hatch-Waxman Act"); 4 n.4 (IMPAX's Offer of Confidential Access is "modeled on statutory provisions applicable to other types of ANDAs"); 7 n. 8 (citing 35 U.S.C. § 271(e)(5) as permitting generic to file declaratory judgment action if patent holder does not sue within 45 days of receiving paragraph IV certification). At the same time, IMPAX exploits the governing framework by seeking to justify its premature filing of this declaratory judgment action despite the absence of harm from a statutory stay. IMPAX's arguments fail as a matter of law. While IMPAX accuses Medicis of seeking to impose "an asymmetric rule" (IMPAX Br. at 6), it is indeed IMPAX that is unfairly seeking an asymmetric application of the Hatch-Waxman Act.

IMPAX also disingenuously asserts that it gave Medicis an opportunity to consider a covenant not to sue and accuses Medicis of making a "calculated decision to delay bringing suit." IMPAX Br. at 1. The facts are directly to the contrary. As explained in our opening brief, Medicis first learned of IMPAX's ANDA submission in January 2008, when Medicis first reviewed the notification letter from IMPAX. IMPAX's letter was received during the holiday and Medicis requested two weeks to provide a substantive response. Medicis Br. at 4. Rather than provide Medicis with that courtesy, IMPAX jumped the gun and filed this lawsuit.

For these reasons the Court should dismiss this action for lack of jurisdiction.

II. In Any Event, This Court Should Exercise its Discretion to Decline Declaratory Judgment Jurisdiction

For the reasons discussed above and in our opening brief (Medicis Br. at 9-10), even if this Court were to conclude that IMPAX had made the required showing of actual injury and an actual controversy (which it has not), numerous "equitable, prudential, and policy" considerations weigh strongly in favor of this Court exercising its "unique and substantial" discretion to decline to exercise jurisdiction over IMPAX's complaint. See MedImmune, 127 S. Ct. at 776-77. IMPAX does not have regulatory approval to commercially market its product and Medicis cannot use its patent to stop or slow FDA approval. IMPAX is seeking an advisory

opinion based on IMPAX's hypothetical injury based on hypothetical FDA approval. The cases cited in our opening brief show that district courts consistently decline to exercise declaratory judgment jurisdiction in these circumstances. Medicis Br. at 10 (citing cases). IMPAX fails to address these cases at all in its opposition brief. IMPAX Br. at 11-13.

Instead, IMPAX conclusorily asserts that the public interest would be served by adjudicating this action because it will "increase competition in the drug industry." Id. at 12. This is wrong. Contrary to IMPAX's assertion, a judgment by this court will not speed the FDA review or approval process and thus cannot enable IMPAX to sell its generic product any sooner. Indeed, as discussed above, allowing IMPAX to proceed in this way would frustrate the framework of the Hatch-Waxman Act, which sets up a scheme in which courts may consider a declaratory judgment claim by a generic only *after* expiration of the 45-day exclusive period in which the patent holder can determine whether and where to sue. See 35 U.S.C. § 271(e)(5). Rather than respect this scheme here, and provide Medicis with a meaningful opportunity to respond to IMPAX's letter as Medicis requested, IMPAX filed this preemptive strike. Rewarding this conduct would run counter to the carefully developed framework of the Hatch-Waxman Act by permitting IMPAX to rely on Medicis' safety and effectiveness data for Solodyn®, developed by Medicis at great time and expense, while racing to the courthouse with this preemptive and premature attack on Medicis' patent rights.

Allowing IMPAX to proceed in these circumstances would also frustrate the policies of the Declaratory Judgment Act by providing an advisory opinion based on a hypothetical approval where Medicis has engaged in no affirmative act with its patent against IMPAX as the cases since MedImmune have required. Allowing a declaratory judgment action to go forward based on no more than the marking of a product, general statements to the investor community, and the absence of a covenant not to sue is without legal support and counter to the policies underlying the Act. In such a scenario, declaratory judgment jurisdiction would become virtually automatic and the courts would be flooded with unlimited requests for advisory opinions based on hypothetical facts.

For these reasons and those set forth in our opening brief, the Court should

exercise its discretion to decline to exercise jurisdiction over IMPAX's complaint.

CONCLUSION

For the foregoing reasons, and those set forth in our opening brief, this Court should grant Medicis' Motion to Dismiss.

Dated: March 28, 2008

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